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Joe Liebeschuetz
Townsend & Townsend & Crew
8th Floor
Two Embarcadero Center
San Francisco, CA 94111-3834

| EXAMINER | |
|---|---|
| CHERNYSHEV, OLGA N | |
| ART UNIT | PAPER NUMBER |
| 1646 | |

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/088,724 | NISHIMOTO, IKUO | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-8,13-16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,13-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/24/2,7/9/2,6/6/3*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I and species election of a polypeptide of SEQ ID NO: 5 in Paper filed on October 16, 2003 is acknowledged.

Claims 3, 9-12, 17 and 19 have been cancelled, as requested in the amendment of Paper submitted on October 16, 2003. Claims 1, 2, 4-8, 13-16 and 18 are pending in the instant application.

Claims 1, 2, 4-8, 13-16 and 18, in so far as they encompass a polypeptide of SEQ ID NO: 5 are under examination in the instant office action.

### *Sequence compliance*

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, no sequence listing has been provided which includes the amino acid sequence presented in claim 1of the instant specification. In case this sequence is new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The

instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

***Drawings***

3. Figures 12, 13, 19 and 25 of the instant application are presented on separate pages or in separate panels. 37 C.F.R. § 1.84(u) (1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. For example, the four panels of Figure 12 in the instant specification should be renumbered "Figure 12A" – "Figure 12D" rather than "Figure 12". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84(u) (1), the specification should be amended to change the Brief Description of the Drawings and the rest of the specification to refer to each Figure accordingly. If, for example, Figure 12 is divided into Figures 12A-12D, then the Brief Description and all the references to this figure in the specification must refer to this Figure in the same manner.

***Specification***

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 47, line 23, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. It is noted that amendment to the specification submitted on January 29, 2004 provided the wrong page for replacement paragraph, perhaps (see page 3 of the amendment, text starting "page 7, line 27", which appears to belong to page 3 of the instant specification instead). Clarification is required.

***Claim Objections***

6. Claims 5-8, 13-16 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 5 depends from claims 1 or 2, which are limited to amino acid sequences, while claim 5 encompasses DNA sequences. Therefore, claims 5, and dependent claims 6-8, 13-16 and 18 can be infringed by a nucleic acid, which does not infringe claims 1 and 2. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim. In the instant case, the nucleic acid claims could be infringed without infringing the claims from which it depends, i.e. the protein claims. Therefore, they are improperly dependent and should be rewritten in independent form.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 2, 5 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims fail to include any limitations which would distinguish the claimed polypeptides and DNA from those which occur in nature. In the absence of the hand of man, naturally occurring nucleic acid molecules and proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 2, 4-8, 13-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Claim 2 encompasses a polypeptide of SEQ ID NO: 5, wherein one or more amino acids have been substituted, deleted, inserted, and/or added, such polypeptide suppresses neuronal death associated with Alzheimer's disease. Claims 4-8, 13-16 and 18 are dependent claims. Applicant is advised that claim 2, as written, encompasses any polypeptide that suppressed neuronal death associated with Alzheimer's disease, including polypeptides with no structural similarity to a polypeptide of SEQ ID NO: 5. The instant specification, as filed, fails to provide any guidance for one skilled in the art on how to make a polypeptide encompassed by claim 2, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the instant invention is the demonstration that a polypeptide of SEQ ID NO: 5, designated Humanin (HN), suppressed *in vitro* neuronal death associated with Alzheimer's disease. This finding appears to be novel because at the time of invention, the art does not recognize the novel polypeptide of SEQ ID NO: 5 as being useful for neuroprotection in association with Alzheimer's disease pathology. However, claim 2, as written encompasses

molecular embodiments that have little or no structural similarity with the instant polypeptide of SEQ ID NO: 5 and yet have a recited function to "suppress neuronal death associated with Alzheimer's disease". First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The instant specification fails to provide any guidance on how to determine which amino acids in SEQ ID NO: 5 are critical to the functional and structural integrity of that protein and which amino acids are expendable. There is no working examples on how to make a polypeptide with no structural resemblance to the instant HN of SEQ ID NO: 5, such polypeptide "suppress neuronal death associated with Alzheimer's disease".

The standard of an enabling disclosure is not the ability to make and test if the invention worked but one of the ability to make and use with a reasonable expectation of success. In view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is not found to be enabling for a polypeptide of SEQ ID NO: 5, wherein one or more amino acids have been substituted, deleted, inserted, and/or added, such polypeptide suppresses neuronal death associated with Alzheimer's disease. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

9. Claims 2, 4-8, 13-16 and 18 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 encompasses a polypeptide of SEQ ID NO: 5, wherein one or more amino acids have been substituted, deleted, inserted, and/or added, such polypeptide suppresses neuronal death associated with Alzheimer's disease. Claims 4-8, 13-16 and 18 are dependent claims. However, the instant specification fails to describe the entire genus of proteins, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 5. The claims are drawn to proteins having one or more amino acids substituted, deleted, inserted, and/or added. First, the claims are not limited to a protein with a specific amino acid sequence. The claims only require the polypeptide to share some degree of structural similarity to the isolated protein of SEQ ID NO: 5. The specification only describes a protein having the amino acid sequence of SEQ ID NO: 5 and fails to teach or describe any other protein which has one or more amino acids substituted, deleted, inserted, and/or added and has activities recited as "suppresses neuronal death associated with Alzheimer's disease". Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was

filed. With this regard, the instant application fails to provide a written description of the species or the genus, which are encompassed by the instant claims. The specification does not provide a complete structure of those polypeptides, wherein one or more amino acids have been substituted, deleted, inserted, and/or added, such polypeptides suppress neuronal death associated with Alzheimer's disease. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those proteins with one or more amino acids substituted, deleted, inserted, and/or added, such proteins, which suppress neuronal death associated with Alzheimer's disease). Therefore, the claims are directed to subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. Claims 13-16 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 13-16 are directed to a pharmaceutical composition comprising HN polypeptide or a vector into which a DNA encoding HN is inserted in amount effective to prevent or treat Alzheimer's disease. However, the instant specification fails to provide enough guidance for one

skilled in the art on how to practice the instant invention, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the invention is the demonstration that HN polypeptide *in vitro* using different cellular systems (primary cultures, cell lines, and transfected cells) suppresses neuronal death associated with Alzheimer's disease (see figures and also Examples on pages 43-60). It is not recognized in the art that HN is involved in neuroprotection related to Alzheimer's disease pathology. However, the instant specification, as filed fails to present any evidence or sound scientific reasoning to support a conclusion that HN polypeptide or a vector into which a DNA encoding HN is inserted can be used in a pharmaceutical composition if systemically administered to treat diseases that are accompanied by neurodegeneration, including Alzheimer's disease.

To use such a pharmaceutical composition would require knowledge of the route, duration and quantity of administration of that protein to a subject and this information is not provided by the instant specification. The instant specification, as originally filed, clearly fails to supply the guidance that would be needed by a routine practitioner. The instant specification has also failed to disclose how these parameters are to be determined, how a similar method was

practiced in the art with a different agent or to provide even a single working example, prophetic or actual, of the claimed method. In the absence of this guidance a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the amount and duration of administration of Humanin or a vector into which a DNA encoding Humanin is inserted of the instant invention and in determining a suitable route of administration. The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a "[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph".

Thus, Applicant's invention is predicated on the finding that Humanin of the instant invention *in vitro* suppresses neuronal death associated with Alzheimer's disease. Applicant further extrapolates this result into a therapeutic application, such a pharmaceutical composition comprising HN or a vector into which a DNA encoding HN is inserted, to treat disease that are accompanied by neurodegeneration. Accordingly, it would appear that Applicant provides a single finding (the finding), and then present an invitation to experiment to determine effectiveness and regime of treatment as well as to assay what diseases that are accompanied by neurodegeneration could be treated by administration of the claimed pharmaceutical.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed invention without first making a substantial inventive contribution.

11. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing the polypeptide of any one claims 1 to 2, comprising the steps of culturing a host cell retaining a vector into which a DNA encoding the polypeptide of any one of claims 1 to 2 is inserted, does not reasonably provide enablement for a method for producing the polypeptide of any one claims 1 to 2, comprising the steps of culturing a host cell retaining a vector into which a DNA encoding a fusion polypeptide comprising the polypeptide of any one of claims 1 to 2 fused with one or more other polypeptides is inserted. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant specification, as filed does not provide any guidance or working examples to teach one skilled in the art on how to practice a method for producing the polypeptide of any one claims 1 to 2 by using DNA encoding a fusion polypeptide comprising the polypeptide of any one of claims 1 to 2 fused with one or more other polypeptides. Because the art does not disclose how to produce a polypeptide using a DNA encoding the fusion polypeptide comprising the intended polypeptide, one skilled in the art would have to resort to undue experimentation in order to be able to practice the full scope of Applicant's invention, as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 8, 13-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 8 is ambiguous and indefinite for recitation "a DNA encoding any one of claims 1 to 2". The metes and bounds of the recitation cannot be determined form the claim.

14. Claim 8 recites the limitation "the expressed polypeptide". There is insufficient antecedent basis for this limitation within the claim.

15. Claim 13 is indefinite for reciting "effective component" with stating an objective what the component is effective for. Clarification is required.

16. Claim 18 is vague and indefinite because the metes and bunds of the limitation "manipulating DNA" cannot be determined from the claim or the instant specification.

17. Claims 14-16 are indefinite for being dependent from indefinite claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by publication NCI CGAP, Genbank Accession No. AA579497, 1997.

Claim 18 is directed to a DNA comprising 15 nucleotides that are omplementary to a DNA consisting of the nucleotide sequence of SEQ ID NO: 4 or to a complementary strand thereof. Genbank Accession No. AA579497 is EST sequence that is 100% identical to 15 nucleotides of the instant SEQ ID NO: 4, see a copy of the sequence alignment attached to the instant office action.

***Double Patenting***

19. Applicant is advised that should claim 13 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 14 adds functional limitation to claim 13, from which it depends. Because there is no other additional limitations, which would change the scope of the claimed subject matter recited in claim 14, the claimed pharmaceutical compositions of the two claims appear to be indistinguishable.

***Conclusion***

20. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER